

EXHIBIT 8



IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA, : CRIMINAL ACTION
Plaintiff :
v. :
ROBERT A. BERKMAN, :
Defendant : NO. 03-45 (JJF)

Wilmington, Delaware
Thursday, July 17, 2003
12:00 o'clock, p.m.

BEFORE: HONORABLE JOSEPH J. FARNAN, JR., U.S.D.C.J.

APPEARANCES:

BETH MOSKOW-SCHNOLL, ESQ.,
Assistant United States Attorney
Counsel for Plaintiff

TERRY K. SHERMAN, ESQ.,
Counsel for Defendant

Valerie J. Gunning
Official Court Reporter

PROCEEDINGS

(Proceedings commenced in the courtroom beginning at 12:00 p.m.)

THE COURT: Good afternoon. Be seated, please.

MS. MOSKOW-SCHNOLL: Good afternoon, your Honor.

Now is the time the Court has set for the change of -- entry of a plea hearing in the case of United States versus Robert A. Berkman, Criminal Action No. 03-45.

I will hand forward the executed memorandum of plea agreement, which also has attached a copy of the settlement agreement.

THE COURT: Thank you.

(Ms. Moskow-Schnoll handed documents to the Court.)

THE COURT: All right. Mr. Sherman, Dr. Berkman, do you want to step up to the podium, please?

MR. SHERMAN: Thank you, your Honor. Good afternoon.

THE COURT: Good afternoon.

THE COURT: Doctor, if you would just take the other side because I'm going to ask you some questions, by where the microphone is. That's perfect.

1 Doctor, as you heard, I've been told by the
2 Government that you are offering to plead guilty and I have
3 to ask you some questions so that I can satisfy myself that
4 you're competent and capable to entering this guilty plea,
5 that you understand the charges that have been brought
6 against you as well as the consequences, and that there's
7 some factual basis for you to plead guilty. All of this is
8 done under oath, so it's important you give truthful
9 responses.

10 If it's later found out your responses were
11 untruthful, the Government can make a decision to charge you
12 with a new and separate crime, such as perjury or making a
13 false statement.

14 Do you understand that?

15 THE DEFENDANT: Yes, I do, your Honor.

16 THE COURT: All right. I will have the clerk
17 administer an oath to you.

18 ... DR. ROBERT A. BERKMAN, having been
19 duly sworn, was examined and testified as
20 follows ...

21 THE COURT: All right. Doctor, first, I'm going
22 to ask you some questions with regard to your waiver of
23 indictment and allowing this case to proceed by an
24 information.

25 Is there a waiver that has been executed?

1 MR. SHERMAN: Your Honor, there has been a
2 waiver.

3 THE COURT: Thank you.

4 I've just been handed up what is captioned a
5 waiver of indictment, and it indicates that you have signed
6 that along with Mr. Sherman.

7 Do you recall signing this?

8 THE DEFENDANT: Yes, I do, your Honor.

9 THE COURT: And do you recall reviewing the
10 contents of it with Mr. Sherman?

11 THE DEFENDANT: Yes, I do.

12 THE COURT: Now, I'm just going to review with
13 you the various paragraphs of this waiver.

14 It says here that you're accused of violating by
15 an information to be filed, 18 United States Code, Section
16 371], conspiracy to violate the Prescription Drug Marketing
17 Act, that you've been advised of the charges and your rights
18 and you're willing to voluntarily, intelligently waive
19 prosecution by indictment and allow the Government to proceed
20 against you simply by filing a piece of paper which we
21 lawyers call an information.

22 Do you understand that?

23 THE DEFENDANT: Yes, I do, your Honor.

24 THE COURT: Do you understand that unless you
25 waive indictment as you've indicated you're willing to do,

1 you couldn't be charged with these crimes unless a Grand Jury
2 were to meet and find that there was probable cause to
3 believe that you've committed the offense you're being
4 accused of and actually voted and returned an indictment
5 against you?

6 THE DEFENDANT: I understand that, your Honor.

7 THE COURT: Do you understand that the Grand Jury
8 is composed of at least 16, but not more than 23 lay people
9 or citizens? At least 12 of those grand jurors would have to
10 find that there was probable cause to believe that you've
11 committed the offenses before you could be indicted, and that
12 by waiving indictment, as I've said, the Government is only
13 going to proceed -- will proceed against you only by filing
14 that sheet of paper.

15 Do you understand that, sir?

16 THE DEFENDANT: I accept that, your Honor.

17 THE COURT: You also understand that in waiving
18 your right to indictment, that Grand Juries actually do meet
19 and vote, and sometimes they vote not to indict a defendant.

20 Do you understand that?

21 THE DEFENDANT: I accept that.

22 THE COURT: All right. Now, has anybody made you
23 any promises or has any anybody threatened you to get you to
24 do this?

25 THE DEFENDANT: Absolutely not, sir.

1 THE COURT: And could you tell me for purposes of
2 the record, you're presently employed as a physician?

3 THE DEFENDANT: Yes, I am.

4 THE COURT: And where are you employed?

5 THE DEFENDANT: Columbus, Ohio.

6 THE COURT: Have you ever been treated for any
7 type of addiction to drugs or alcohol?

8 THE DEFENDANT: Absolutely never.

9 THE COURT: Have you ever been treated for any
10 type of psychiatric or psychological disorder, what we would
11 commonly refer to as a mental illness?

12 THE DEFENDANT: Never, sir.

13 THE COURT: In the last 24 hours, have you drank
14 any alcoholic beverages?

15 THE DEFENDANT: No, sir. I don't drink, sir.

16 THE COURT: All right. Have you taken any drugs,
17 legal or illegal, that could affect your ability to
18 understand the proceedings here today?

19 THE DEFENDANT: Absolutely not, sir.

20 THE COURT: And you feel competent you've had a
21 fair opportunity to consult with Mr. Sherman, who's your
22 attorney in this case, and you're satisfied with his
23 representation?

24 THE DEFENDANT: Yes, I am, sir.

25 THE COURT: Okay. Based on the responses you've

1 given me here today, then, I'm going to accept your waiver of
2 indictment, finding that you are capable to do it and
3 competent and it's being done voluntarily, without any threat
4 or coercion, and I will file it with the clerk in open court
5 at this time.

6 I'm now going to proceed to ask you some
7 questions about your offer of a guilty plea to the
8 information that the Government has filed, which is that
9 piece of paper I talked about when we spoke with regard to
10 your waiver of indictment.

11 If I asked you all of those questions about your
12 present employment, use of drugs or alcohol, all of those
13 answers would be the same as we begin to discuss this
14 criminal charge?

15 THE DEFENDANT: Yes, sir.

16 THE COURT: Have you had an opportunity to review
17 in detail the charges the Government alleges in this
18 information with Mr. Sherman?

19 THE DEFENDANT: Yes, I have, sir.

20 THE COURT: Are you satisfied you understand the
21 charges the Government brings against you?

22 THE DEFENDANT: Yes, sir, I do.

23 THE COURT: I need you to tell me in your own
24 words what conduct you engaged in that makes you believe
25 you're guilty of this information.

1 THE DEFENDANT: I have violated federal law, your
2 Honor. I should have understood that the Medicare system was
3 a reimbursement system and that it was not a for-profit
4 system. That was my first error.

5 The second was when I was engaged in the use of
6 the medication Zoladex and the pharmaceutical company,
7 AstraZeneca, presented to me incentives relative to the
8 purchase and securement of the medication, and advising me
9 that it could be used for enhancing revenues in my practice
10 by virtue of purchase agreements and incentives and
11 implications, I accepted them, your Honor.

12 I take responsibility for that. They purported
13 that it was appropriate. I realize now that it was not and
14 the discounts that I received, I realize that I should have
15 reported them, but I did not.

16 THE COURT: All right. And you understand that
17 all of that was illegal and in violation of federal criminal
18 statute?

19 THE DEFENDANT: Yes, sir, I now do.

20 THE COURT: I'm going to ask the prosecutor, Ms.
21 Moskow-Schnoll, to provide us with an offer of evidence the
22 Government would have presented against you had this case
23 gone to trial.

24 Ms. Moskow-Schnoll?

25 MS. MOSKOW-SCHNOLL: Your Honor, Astra-Zeneca

1 Pharmaceuticals LP is a pharmaceutical company headquartered
2 in Wilmington, Delaware. The defendant is a urologist
3 licensed to practice medicine in the State of Ohio, with a
4 practice located in Columbus Ohio.

5 Zoladex is a drug used in the treatment of
6 prostate cancer. The drug is manufactured and marketed by
7 Astra-Zeneca. Medicare reimburses for injectable drugs such
8 as Zoladex based upon the average wholesale price or AWP for
9 such drugs as published in the pharmaceutical industry
10 reference known as the Redbook.

11 The Zoladex AWP published in the Redbook was a
12 number supplied by Astra-Zeneca. In effect, this allowed
13 Astra-Zeneca to control the amount of reimbursement Medicare
14 paid to physicians for prescriptions.

15 Because Astra-Zeneca charged urologists less than
16 the published AWP for Zoladex, a physician could earn a
17 profit by choosing to treat a prostate cancer patient with
18 Zoladex. Astra-Zeneca referred to this profit as return to
19 practice.

20 In addition to the return to practice, in
21 order to induce physicians to purchase or to continue
22 purchasing Zoladex, Astra-Zeneca provided free samples
23 of the drug to physicians, both intending and expecting
24 that certain of those physicians would administer the free
25 samples and thereafter bill their patients and their

1 patients' insurers.

2 Specifically, when Dr. Berkman stated that he
3 would switch his patients from Zoladex to Lupron if he did
4 not get a better deal from Astra-Zeneca, Astra-Zeneca
5 provided free injections of Zoladex.

6 In this way, beginning in or around February 1994
7 and continuing at least until July 1996, Astra-Zeneca sales
8 representatives provided to Dr. Berkman approximately 223
9 free one-month sample doses of Zoladex. Each sample was
10 labeled not for retail sale and Dr. Berkman signed a sample
11 receipt card for each sample dose he received. At least one
12 Astra-Zeneca sales representative additionally provided Dr.
13 Berkman's office with labels that Dr. Berkman's staff used to
14 cover up the not-for-resale statement on the packaging.

15 Dr. Berkman administered the free samples and
16 received approximately \$84,448 in billing for the free
17 samples.

18 THE COURT: Doctor, you've heard what the
19 prosecutor says the evidence the Government would have
20 brought against you is.

21 Do you have any strong disagreement with that
22 evidence?

23 THE DEFENDANT: No, sir. I have no
24 disagreement.

25 THE COURT: Mr. Sherman?

1 MR. SHERMAN: Well, your Honor, the free Zoladex
2 that was provided to Dr. Berkman was represented to him as
3 part of a volume discount, and that's -- and the second thing
4 I think the record ought to clearly represent is the use of
5 Zoladex by Dr. Berkman was never motivated to the patient.
6 It was motivated by the need of the patient to receive the
7 drug.

8 There was no issue that the patients that
9 received Zoladex shouldn't have received it or that treatment
10 in another fashion would have been more appropriate.

11 THE COURT: All right. With those two further
12 understandings of Dr. Berkman's view of the Government's
13 evidence, is there anything additional?

14 MR. SHERMAN: Not at this time, your Honor.

15 THE COURT: All right. Doctor, do you agree with
16 what Mr. Sherman has told us?

17 THE DEFENDANT: Yes, sir, I do.

18 THE COURT: Okay. I'm going to ask you about the
19 memorandum of plea agreement and what I guess is an
20 attachment. It's called the Settlement Agreement Between the
21 Office of Inspector General and the Department of Health and
22 Human Services and Robert A. Berkman, M.D.

23 Have you reviewed both the memorandum of plea
24 agreement and this settlement document?

25 THE DEFENDANT: Yes, sir, I have.

1 THE COURT: And have you talked with Mr. Sherman
2 about both of these documents?

3 THE DEFENDANT: I have, your Honor.

4 THE COURT: And in the memorandum of plea
5 agreement, it says in Paragraph 1 that the violation you're
6 pleading guilty to carries a maximum penalty of imprisonment
7 of not more than five years and a \$250,000 fine, three years
8 of supervised release and a \$100 special assessment.

9 Do you understand that they're the maximum
10 penalties you're exposing yourself to buy your guilty plea
11 here today?

12 THE DEFENDANT: I do, your Honor.

13 THE COURT: And do you also understand that there
14 are sentencing guidelines in place in Federal Court and
15 you'll be sentenced in accordance with those guidelines
16 unless there's some reason, either that there should be a
17 departure upwardly or downwardly, which would have to be
18 justified?

19 THE DEFENDANT: I accept that, your Honor.

20 THE COURT: And do you understand all the
21 provisions of this memorandum of plea agreement? This is the
22 time to ask questions about it if you don't.

23 THE DEFENDANT: I understand it, sir.

24 THE COURT: And on the copy that has been given
25 to me, there's a signature there. Is that your signature

1 along with Mr. Sherman's?

2 THE DEFENDANT: Yes, sir, it is.

3 THE COURT: Now, are all the promises you've
4 received from the United States Government to get you to
5 enter into this plea agreement which relates to the criminal
6 charge and the settlement agreement with the Inspector
7 General, are all the promises or guarantees or matters in
8 exchange you've gotten contained in these two documents?

9 THE DEFENDANT: I received no promises, sir,
10 other than the document. It's just the document. That's all
11 I received.

12 THE COURT: Sometimes defendants come back and
13 they say, Well, gosh, I was told this and I know it wasn't in
14 the agreement. But what I want to be sure is everything you
15 have discussed and been told would be given in exchange to
16 get your plea and to get the settlement agreement they're all
17 in the documents; correct?

18 THE DEFENDANT: There was nothing else, sir.
19 Just the document.

20 THE COURT: Is anybody threatening you or in any
21 way forcing you to plead guilty?

22 THE DEFENDANT: No, sir.

23 THE COURT: Has anybody promised you what the
24 sentence will be?

25 THE DEFENDANT: No, sir.

1 THE COURT: I'm now going to review with you your
2 rights as a defendant.

3 Do you understand you have the absolute right to
4 continue to plead not guilty and no one could force you to
5 plead guilty, and understand that the burden is always on the
6 United States Government to prove your guilt in this criminal
7 charge by a standard of beyond a reasonable doubt?

8 THE DEFENDANT: I accept that.

9 THE COURT: Do you understand that if you told me
10 that you wanted to continue to plead not guilty, that I would
11 schedule a trial and 12 jurors would be impaneled to sit and
12 hear your case?

13 THE DEFENDANT: I'm aware of that, sir.

14 THE COURT: Do you understand at that trial you
15 would have the right to be represented by an attorney, in
16 this case Mr. Sherman, and you could, through your attorney,
17 challenge the Government's evidence, both exhibits and
18 testimony?

19 THE DEFENDANT: I understand that, sir.

20 THE COURT: Do you understand that you could
21 also, through your attorney, present evidence on your behalf,
22 both witnesses and exhibits, and that you could use the power
23 of the Court to subpoena persons or documents that you
24 thought might favor your case to be forced to be brought to
25 Court here?

1 Do you understand that?

2 THE DEFENDANT: Yes, I do.

3 THE COURT: Do you also understand, as I've told
4 you, that you don't have to do anything during the trial
5 because the burden is always on the Government, not on the
6 defendant. And, in addition, you have an absolute right
7 against self-incrimination, so you could just sit through the
8 trial and not have to say anything.

9 Do you understand that?

10 THE DEFENDANT: I do.

11 THE COURT: Do you understand if you wanted to
12 testify in your cause, after consultation with your attorney,
13 you could make a decision to testify?

14 THE DEFENDANT: Yes, sir, I understand that.

15 THE COURT: Do you understand that for you to be
16 found guilty, all 12 jurors would have to agree that you were
17 guilty. In other words, their verdict would have to be
18 unanimous?

19 THE DEFENDANT: I understand that.

20 THE COURT: Do you understand if that jury were
21 to find you guilty by unanimous vote, that you could appeal
22 their decision to a higher Court, the Court of Appeals for
23 the Third Circuit in Philadelphia?

24 THE DEFENDANT: Yes, sir, I do.

25 THE COURT: Do you also understand that when you

1 plead guilty, there is no appeal from the facts of the case
2 because you've admitted you're guilty. You can appeal the
3 sentence if you believe any part or all of it is illegal, but
4 there's no appeal from your guilt or innocence determination
5 because you admitted guilt?

6 THE DEFENDANT: I accept that.

7 THE COURT: Do you understand that all the rights
8 I've discussed with you and your right to a jury trial are
9 being given up or waived by you by your entry of this guilty
10 plea?

11 THE DEFENDANT: I do, sir.

12 THE COURT: Do you also understand that as a
13 convicted felon, you are going to lose valuable civil rights,
14 such as the right to vote, the right to ever hold public
15 office and the right to ever be around or near firearms and
16 other consequences that may pertain from jurisdiction to
17 jurisdiction that I'm not mentioning here, but what I want
18 you to understand is that being a convicted felon carries
19 with it penalties in addition to the sentence that would be
20 imposed in this case.

21 Do you understand that, sir?

22 THE DEFENDANT: I accept that.

23 THE COURT: Mr. Sherman, do you know anything
24 else I should ask Dr. Berkman?

25 MR. SHERMAN: No, your Honor. I think you're

1 doing quite well.

2 THE COURT: Ms. Moskow-Schnoll, do you know
3 anything else I should ask Dr. Berkman?

4 MS. MOSKOW-SCHNOLL: No, your Honor.

5 THE COURT: Dr. Berkman, based on the responses
6 you've given here today, I find you're competent and capable
7 to enter a guilty plea. I further find that you are fully
8 aware of the charges against you and the consequences that
9 will flow from this guilty plea. I further find there's a
10 basis in fact for you to plead guilty to this information,
11 both by your own admission of guilt and your acceptance of
12 the clarifications made by Mr. Sherman of the Government's
13 offer of proof.

14 For all of these reasons, I now adjudge you
15 guilty of the information count and ask you to indicate your
16 guilty plea by signing the information when presented it by
17 the Clerk of the Court.

18 I'm going to indicate my acceptance of your
19 guilty plea by signing the memorandum of plea agreement and
20 filing it in open court with the clerk at this time.

21 DEPUTY CLERK: The information has been signed,
22 your Honor.

23 THE COURT: All right. Dr. Berkman, someone
24 from our presentence office will be contacting you as well as
25 Mr. Sherman. It's important you cooperate with that officer

1 so I will have all the information you want me to have when
2 the time comes for sentencing.

3 I'm going to have sentencing scheduled by my
4 office contacting Mr. Sherman and Ms. Moskow-Schnoll and it
5 will be in approximately three months, and we'll get that
6 date probably in the next 30 days.

7 Mr. Sherman, is there anything further.

8 MR. SHERMAN: No, your Honor.

9 THE COURT: Ms. Moskow-Schnoll?

10 MS. MOSKOW-SCHNOLL: No, your Honor.

11 THE COURT: All right. This matter then may
12 stand in recess. I have another matter to take up.

13 (Court recessed at 12:18 p.m.)

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I hereby certify that the foregoing is a true
and accurate transcript from my stenographic
notes in the proceeding.

23

Valerie J. Blum

24

Official Court Reporter
U. S. District Court

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12 IN RE: USA v. ROBERT A. BERKMAN
13 CRIMINAL ACTION NO. 03-41 (JUF)
14 DISTRICT OF DELAWARE

15 CHANGE OF PLEA HELD THURSDAY, JULY 17, 2003 BEFORE JUDGE
16 FARNANIN IN WILMINGTON, DELAWARE.

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18 THANK YOU.
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